

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

INHIBITOR OF HEPATITIS B AND HIV ACTIVITY

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as

Application Serial No. _____

and was amended on _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

317564/1993 Japan 17.Dec., 1993
(Number) (Country) (Day/Month/Year Filed)

☒ Yes ☐ No

(Number) (Country) (Day/Month/Year Filed)

☐ Yes ☐ No

(Number) (Country) (Day/Month/Year Filed)

☐ Yes ☐ No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

COPY

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

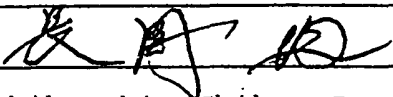
William H. Webb	13,467	David C. Hanson	23,024	Paul M. Reznick	33,059
John M. Webb	20,150	Richard L. Byrne	28,498	Raymond J. Harmuth	33,896
David C. Bruening	20,742	Frederick B. Ziesenheim	19,438	John W. McIlvaine	34,219
William H. Logsdon	22,132	Kent E. Baldauf	25,826	Michael I. Shamos	30,424
Russell D. Orkin	25,363	Barbara E. Johnson	31,198	Blynn L. Shideler	35,034

Send Correspondence to:

Russell D. Orkin, Esq.
700 Koppers Building
Pittsburgh, PA 15219-1818

Direct Telephone Calls to: *(name and telephone number)*

Russell D. Orkin - 412-471-8815

Full name of sole or first inventor		Hitoshi NAGAOKA
Inventor's signature		Date June 1, 1994
Residence Abiko-shi, Chiba, Japan		
Citizenship Japanese		
Post Office Address 22-13, Kotobuki 2-chome, Abiko-shi, Chiba 270-11,		
Japan		
Full name of second joint inventor, if any		
Second Inventor's signature		Date
Residence		
Citizenship		
Post Office Address		

(Supply similar information and signature for third and subsequent joint inventors.)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : Not Yet Assigned
Applicant : Hitoshi Nagaoka
Filed : Concurrently Herewith
Title : INHIBITOR OF HEPATITIS B AND HIV ACTIVITY

MAIL STOP PATENT APPLICATION

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

COMMUNICATION

Sir:

Applicant submits herewith a copy of the Declaration of Hideo Sawadaishi, dated February 28, 2003, which was submitted in parent United States Application Serial No. 08/519,293 on March 19, 2003. The significance of the Declaration is explained below.

In the Decision on Appeal mailed December 30, 2002, the Board of Appeals vacated the Examiner's rejection of claims 11, 12 and 16-18 under 35 U.S.C. § 103 as obvious in view of Iizuka, Sugano, Nagaoka I, and Nagaoka II, and entered a new ground of rejection of claims 11, 12 and 16-18 under 35 U.S.C. § 102(b) as anticipated by Nagaoka III. According to the Board, the claims on appeal were directed to a method of making an extract and to the extract so made, not to a method of treating a viral infection.

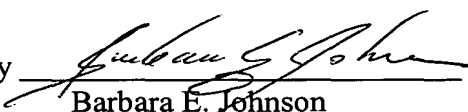
To overcome this rejection, Applicant has presented herewith new claims that are directed to a method for treating viral diseases such as human immunodeficiency virus, Hepatitis B infection, and liver cancer. It is well established that a new use for an old product may be claimed as a method. *Ex parte Muller*, 81 U.S.P.Q. 261 (Patent. Off. Bd. App. 1947). The Federal Circuit has held that “claims drawn to a new method for using either an old or ‘obvious’ composition, wherein the method has unobvious beneficial or useful effects, have been found patentable even though the composition itself could not be patented.” *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983). Thus, Applicant submits that the new method of treatment claims overcome the outstanding art rejection, by virtue of the new and unexpected results attributable to the claimed invention.

Corroborating evidence is provided, in the accompanying Declaration of Hideo Sawadaishi, to underscore the new and unexpected results achievable with the invention as claimed. Hideo Sawadaishi is an expert familiar with the subject matter of the application. In the Declaration, Mr. Sawadaishi attests to the remarkable and unexpected effects of the *Lentinus edodes* mycelium extract on fifty-eight patients infected with Hepatitis B virus. Mr. Sawadaishi reports, in Paragraph 3 of his Declaration, the particulars of the study and the conclusions the study supports. Chronic treatment with the extract according to claim 1 resulted in 72% of the patients seroconverting from Hepatitis B “e” (Hbe) antigen positivity to negativity (a serum marker for Hepatitis B virus infection), as well as showing a significant and remarkable improvement in their serum liver enzyme values without adverse side effects. Mr. Sawadaishi concludes, at the end of Paragraph 3 of the Declaration, that the subject matter of claim 1 recites a way of treating viral diseases which accomplishes new and unexpectedly efficacious results, as compared to conventional treatment or no treatment. These unexpected results as corroborated by Mr. Sawadaishi’s Declaration are entitled to greater weight than any assertion to the contrary for which no factual basis or showing might be brought forth. Applicant thus believes that it has now met all its obligations necessary for allowance of this patent application.

In light of the above, the subject application is believed to be in condition for allowance, and notice to that effect is earnestly solicited. If the Examiner believes that further claim amendments are necessary, she is urged to contact the undersigned at 412-471-8815.

Respectfully submitted,

WEBB ZIESENHEIM LOGSDON
ORKIN & HANSON, P.C.

By 
Barbara E. Johnson
Registration No. 31,198
700 Koppers Building
436 Seventh Avenue
Pittsburgh, PA 15219-1818
Attorney for Applicants
Telephone: (412) 471-8815
Facsimile: (412) 471-4094
E-mail: webblaw@webblaw.com